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MERGED PROCEEDINGS

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Inventors: AINSWORTH et al.

Patent No. 5,554,121

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For: INTRALUMINAL CATHETER WITH HIGH STRENGTH PROXIMAL SHAFT

Examiner: Sharon Kennedy

Art Unit: 3762

Sent via electronic transmission

August 27**, 2008**

George Wheel
Reg. No. 28,766

DECLARATION OF INVENTORS
UNDER 37 C.F.R. § 1.131

( ) Mail Stop Reissue
( ) Mail Stop Ex Parte Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

1. We, Robert Ainsworth and Lawrence Wasicek, are two of the three co-inventor of the inventions claimed in the above-identified patent application, and former employees of the assignee, Advanced Cardiovascular Systems, Inc. ("ACS"). The other co-inventor is Mr. Tai Cheng. All three co-inventors were employees of ACS at the time the present invention was made, but are no longer employees of

ACS or its successors. Unless otherwise indicated or apparent, "we" or other plural pronouns in this declaration refer to all co-inventors. Unless otherwise indicated, all activity described in this declaration occurred in the United States.

2. We, Robert Ainsworth and Lawrence Wasicek, do not know where Mr. Tai Cheng is or how to find him. We therefore believe he is presently unavailable to participate in preparing, reviewing, or signing this declaration.

Conception Prior To The Diligence Period

3. Prior to **January 20, 1994**, we conceived the idea of using a balloon dilatation catheter comprising a proximal shaft formed at least in part of an extruded engineering thermoplastic polymeric material as later described and claimed in our U.S. Patent No. 5,554,121. Inventor Cheng disclosed his contribution to the conception of the invention, for example, in Exhibit 1. Exhibit 1 is an invention disclosure signed by Mr. Cheng on **July 29, 1993**. The Cheng disclosure was sent by interoffice mail to the Patent Department of ACS for handling in the ordinary course.

4. Exhibit 2 attached to this declaration is a document Robert Ainsworth completed on or about **August 26, 1993**, indicating his intention to develop a catheter having a PEEK proximal shaft. At least by that date we had ordered some "PEEK" (polyetheretherketone) resin and conceived of its utility as a material for the shaft of a balloon dilatation catheter. We made this conception after ACS determined the properties of an extruded sample of tubing and we found that it had a higher elongation than its published specification and other suitable properties. The Materials Test Report attached as Exhibit 3 documents this work. This report indicates an average "Strain at Break" for a sample of PEEK tubing of "6.95E-1" – 0.695 – which represents 69.5% elongation. Exhibit 2 also documents the large amount of activity that was required to develop and market a balloon dilatation

catheter having a PEEK proximal shaft, and a forecast of the amount of time we would require to complete this work.

Reasonable Diligence During The Diligence Period

5. Inventor Wasicek made an inventive contribution to the present invention at least by the time of a "brainstorming meeting" of **January 13, 1994**. This meeting was held at ACS to discuss new materials for construction of the proximal shaft of a balloon dilatation catheter. This meeting is documented by Exhibit 4, which contains as the second-to-last page a memo dated **January 14, 1994**, recording the substance of the meeting.

6. We therefore conceived our invention before **January 20, 1994**, as documented by Exhibits 1-4.

7. We constructively reduced our invention to practice, as that concept has been explained to us, by filing a patent application directed to our invention. The application was U.S. Serial No. 280,210 filed **July 25, 1994**, which later issued as U.S. Patent No. 5,554,121.

8. During the period from just before **January 20, 1994,** to **July 25, 1994**, we were continuously diligent, both by our direct efforts and by the efforts of our fellow ACS employees, in working to reduce the invention of our U.S. Patent No. 5,554,121 to practice. The following paragraphs of this declaration document our diligent efforts during the period just mentioned. In this declaration, we will refer to the period from just before **January 20, 1994,** to **July 25, 1994,** as the "diligence period."

9. While we have not presented documentation dated on every day of the diligence period, we have collected a wide variety of different documents, prepared by many different ACS employees at short intervals over the entire diligence period.

These documents show that our efforts to reduce the invention to practice were substantially continuous during the entire diligence period. Even on dates for which we do not have a specific document attached, our co-workers and we were diligently working to reduce the invention to practice.

10. Our diligent efforts began at least by **January 13, 1994**, when we called the "brainstorming meeting" discussed above and documented in a memo drafted on **January 14, 1994,** and included as part of Exhibit 4. Inventor Wasicek wrote the memo and sent it to others and us.

11. On **January 20, 1994**, ACS employee Lucy Mariano carried out a differential scanning calorimeter test to assure that tubing we had recently obtained from a supplier was made of PEEK. That testing is documented by a report, Exhibit 5, dated **January 21, 1994**. We concluded from this test that the material of the tubing was indeed PEEK.

12. On **January 24, 1994**, Eric Leopold, our fellow employee who worked for us on this project, tested proximal shaft designs. Mr. Leopold established that a PEEK proximal shaft of a rapid exchange catheter was bondable to the adjacent elements of the shaft. The "New Platform" memorandum attached as Exhibit 6, at page A10, documents this testing.

13. On **January 25, 1994**, and on numerous other occasions, balloon dilatation catheters made with a PEEK or similar engineering plastic proximal shaft were tested to determine the suitability of that shaft in such a catheter. One such test was a "heart model" test. A heart model test is carried out on a plastic replica of a human heart and other vasculature leading back to a femoral artery. The heart models have approximately the geometry and dimensions of representative human anatomy. These tests are carried out to determine whether the prototype catheter has many of the necessary characteristics of a dilatation catheter. One

characteristic measured by this test is kink-resistance, and another is pushability of the catheter – the ability to push it into the desired coronary artery by manipulating its proximal portion from outside the heart model.

14. On **January 25**, **1994**, ACS carried out heart model tests of four dilatation catheter prototypes having PEEK outer shafts. These prototypes were compared to two prototype catheters using Elastinite® nickel-titanium alloy metal shafts. Elastinite® nickel-titanium alloy was another material ACS was testing for its suitability as a catheter shaft, although its high cost was a serious disadvantage. One of the goals of the present testing and development program was to provide an extrudable plastic shaft that had as many characteristics as possible of the more expensive Elastinite® nickel-titanium alloy shaft. This testing is documented in Exhibit 6, at page A14.

15. On **January 28, 1994**, ACS held an update presentation and meeting to review the developments respecting the use of a PEEK catheter shaft. This meeting is documented by the document entitled "Concept Template" attached as Exhibit 7. This document also provides an idea of the large amount of effort required to develop a proximal shaft made of engineering thermoplastic material such as PEEK.

16. On **February 1, 1994**, we ordered 50,000 feet of PEEK tubing in several sizes from a company known as Acutech. We ordered this PEEK tubing expressly for the purpose of developing a new proximal shaft for balloon dilatation catheters. We ordered this large amount of tubing because we wanted to have it continuously available for the period of our development, to the extent possible. This order is documented by a purchase order dated **February 1, 1994,** and an accompanying acknowledgment of the same date in which Acutech promised to ship this material by **March 2, 1994**. This purchase order and corresponding acknowledgment are attached as Exhibit 8.

17. On information and belief, on **February 1, 1994**, ACS had little PEEK tubing available, and ACS had not yet developed the ability to manufacture suitable PEEK tubing itself. We were unable to experiment with prototype catheters having PEEK proximal shafts to any substantial degree until this material was received. The tubing was in fact received on **March 9, 1994** (see the March 9 entry below).

18. During the period from about **January 13, 1994,** through **February 1994**, inventor Wasicek was collecting literature from suppliers of engineering thermoplastic polymers. His purpose was to determine which materials had specifications which would qualify them for further testing to determine whether they would be suitable for fabricating the proximal shafts of angioplasty balloon catheters. Exhibit 9 – a memorandum entitled "Advanced Thermoplastics, Elastinites Alternative Materials" and its attachments, documents this work.

19. On **February 11, 1994**, a senior staff presentation meeting was held. The materials presented at the senior staff presentation were instrumental in enabling us to proceed toward development and eventual commercialization of a balloon dilatation catheter having a PEEK proximal shaft. Documentation of this meeting is provided in Exhibit 6 on page A9.

20. On Tuesday **February 15, 1994**, inventor Wasicek received a facsimile message from BASF (a supplier of engineering thermoplastics). This facsimile, documented in Exhibit 9, included property sheets for several engineering thermoplastic materials made by BASF.

21. On Thursday, **February 17, 1994**, inventor Wasicek sent a memorandum to us and others collecting the published information inventor he had collected on advanced thermoplastics to replace Elastinite® nickel-titanium alloy. This memorandum is attached as Exhibit 9.

22. On **February 22, 1994**, a laboratory technician at ACS prepared PEEK material for a cytotoxicity and hemolysis test. These are tests that determine the biocompatibility of a material. A material must be biocompatible to be useful for incorporation in a balloon dilatation catheter. Dennis Houlsby documented the biocompatibility test results on PEEK, and specifically Victrex 381G PEEK material. A memorandum documenting this work is attached as Exhibit 10.

23. On **February 24, 1994**, employees of ACS carried out heart model testing of a "New Platform RX" balloon dilatation catheter prototype. Exhibit 6 documents this work on page A10. This work was cited in Exhibit 6 as one basis for electing PEEK proximal shaft tubing for use in an RX ("rapid-exchange") catheter. An RX catheter is one type of catheter according to the present invention.

24. On **February 25, 1994**, hemolysis testing was completed for the PEEK 381G material from Acutech as documented in the **March 4, 1994,** entry below. Exhibit 10 documents this date.

25. On **February 28, 1994**, the cytotoxicity testing described and documented in the memo dated **March 4, 1994**, was completed. Exhibit 10 documents this date.

26. On **March 1, 1994**, Robert Ainsworth held an advanced thermoplastics meeting with other ACS employees working on the PEEK project to discuss alternatives to Elastinite® nickel-titanium alloy tubing. A memorandum dated March 2, 1994, pasted into laboratory notebook 1260 at pages 37 and 53, documents this meeting. This memo is attached to the last page of Exhibit 4.

27. On **March 4, 1994,** Dennis Houlsby sent a memorandum documenting the results of his biocompatibility test results on PEEK (Acutech-extruded Victrex 381G) material. Mr. Houlsby concluded that the material he tested passed the biocompatibility testing he carried out. Exhibit 10 documents this.

28. From **March 7 to 11, 1994**, Dick Hock, a fellow employee, was assigned the task of extruding PEEK tubing that would be suitable for use as the proximal shaft of a balloon dilatation catheter. This work is documented by Exhibit 4, the last page, to which is attached a memo dated **March 2, 1994,** documenting that this task was assigned.

29. Inventor Wasicek prepared a memo that is found in Exhibit 4, at page 53, including a hand-written note that PEEK tubing was received from Acutech, identified as "the outside vendor," on **March 9, 1994**. Once this tubing was received, we were able to continue our work on an accelerated basis.

30. On **March 9 and 10, 1994**, an animal study was carried on a "new platform RX" balloon dilatation catheter. The proximal shafts of these catheters were in at least some cases fabricated from Victrex 381G PEEK tubing. An animal study was carried out on a pig and an expired pig in different tests carried out at the Mayo clinic by Drs. Rob Schwartz and Tony Farrah. This animal study is documented by Exhibit 6, pages 32-33.

31. On **March 10, 1994**, ACS employees working at the direction of the inventors extruded some PEEK tubing for use in prototype balloon dilatation catheters. An Extrusion Data Sheet dated March 10, 1994, attached as Exhibit 11, documents this extrusion work. Therefore, at least by **March 10, 1994**, ACS employees were working in two parallel courses to reduce the present invention to practice. We were attempting to reduce the invention to practice using the PEEK tubing made by Acutech. We also were extruding our own PEEK tubing and evaluating its suitability for fabricating balloon dilatation catheter proximal shafts as described in our patent.

32. On **March 11, 1994**, inventor Wasicek had been assigned the task of ordering materials other than PEEK for evaluation as possible engineering thermoplastic materials for fabrication of balloon dilatation catheter proximal balloon shafts. The specific materials to be ordered, which we believe were in fact ordered on or about that date, were polyethersulfone ("PES"), PAEK (polyaryletherketone), polyphenylene sulfide ("PPS"), and polyetherimide ("PEI"). This work is documented by Exhibit 4, the last page (page 53). Also on **March 11, 1994**, ACS employees made an additional sample of PEEK tubing. This work on that date is documented in an Extrusion Data Sheet dated **March 11, 1994**, attached as Exhibit 12.

33. On **March 14, 1994**, Ted Slater ("TAS") of ACS tested the mechanical properties of a sample of PEEK engineering thermoplastic material tubing for its suitability as the proximal shaft of a balloon dilatation catheter. Looking at the two extremes, in one instance he obtained a 156% elongation at break, and in another sample he obtained an elongation of 59% at break. The Materials Test Reports attached as Exhibit 13 document this testing.

34. On **March 15, 1994**, Ted Slater prepared another Materials Test Report testing the properties of PEEK shaft material. The Materials Test Report is attached as Exhibit 14.

35. On **March 16, 1994**, inventor Wasicek prepared a report entitled "Summary of Materials Under Evaluation for Next OTW. "OTW" stands for "Over-The-Wire" – a type of balloon dilatation catheter illustrated in the figures of U.S. Patent No. 5,554,121. Exhibit 6 at Page A9 documents this date. On **March 16, 1994**, the inventors and others conducted an advanced thermoplastics meeting where the materials for the proximal shaft, and particularly engineering thermoplastic materials for the proximal shaft, were discussed.

36. On **March 24, 1994**, several pertinent events are documented. On this date John Shanahan, one of our co-workers, presented a Passport Roman II concept review, which contributed to our decision for electing PEEK as the proximal shaft for a rapid exchange catheter, which would be a balloon dilatation catheter. This review is documented by Exhibit 6, page A10.

37. On Friday **March 25, 1994**, an ACS employee named T. Tomas extruded PEEK tubing for use in making prototype proximal shafts for balloon dilatation catheters. This work is documented in Exhibit 15.

38. On **March 28, 1994**, we extruded additional tubing made of engineering thermoplastic material (PPS). PEEK tubing was also made on the same date. The Extrusion Data Sheets of Exhibit 16 document this work.

39. On **March 29, 1994**, ACS personnel extruded additional PEEK tubing of various dimensions under various conditions. This work is documented by the Extrusion Data Sheets dated **March 29, 1994**, attached as Exhibit 17. Also on **March 29, 1994**, heart model testing of two different balloon dilatation catheter prototypes having PEEK proximal shafts was carried out. This work is documented by Exhibit 6, page A15.

40. On **March 31, 1994**, ACS personnel extruded PPS engineering thermoplastic polymer tubing for the proximal shaft of a balloon dilatation catheter prototype. Exhibit 18 documents this work.

41. On **April 4, 1994**, ACS employees tested PEEK tubing for its ability to withstand irradiation, which is used to sterilize a catheter. A page from Robert Ainsworth's day timer documents this work for **April 4, 1994**, attached as Exhibit 19. On the same day, ACS extruded additional Fortron polyphenylene sulfide (PPS) tubing for testing as an appropriate proximal shaft material for balloon dilatation

catheters. The Extrusion Request Form dated April 4, 1994, attached as Exhibit 20, documents this work.

42. On **April 6, 1994**, Robert Ainsworth held a staff meeting at ACS on the ".014 Platform" project, which was then our project name for a balloon dilatation catheter for which we were developing an engineering plastic proximal shaft. Exhibit 21, a page from Robert Ainsworth's day timer, documents this work.

43. On **April 8, 1994**, ACS employee T. Tomas extruded some polyethersulfone ("PES") tubing for use as the proximal shaft of prototype balloon dilatation catheters. In this and other extrusion work, ACS was determining what conditions should be used and what materials should be used to make tubing that would be satisfactory for use in the proximal shaft of a balloon dilatation catheter. Exhibit 22, an Extrusion Data Sheet, documents this work.

44. On **April 14, 1994**, Robert Ainsworth set up a meeting with Dave Young, a co-employee at ACS, to discuss the use of PEEK for the proximal shaft of balloon dilatation catheters. While Robert Ainsworth doesn't recall the specific meeting, he believes it was his intention to discuss where PEEK could be purchased. This work is documented by Exhibit 23, which is a copy of his day timer page for **April 14, 1994**.

45. On **April 15, 1994**, Robert Ainsworth was considering the subject of the extrusion of PEEK, most probably what extrusion conditions gave the best results from the point of view of using the product as the proximal shaft of a balloon dilatation catheter. His day timer page for **April 15, 1994**, which is Exhibit 24, documents this work.

46. On **April 18, 1994**, ACS employee T. Tomas was requested by Jeong Lee of Robert Ainsworth's project core team to extrude PAEK material for the "Low-

Profile Shaft." The "Low-Profile Shaft" is a more specific name for the extruded engineering thermoplastic proximal shaft for a balloon dilatation catheter under development at that time. This work was continued on **April 19, 1994**. The attempt to extrude this material was not successful, as several problems are noted on the Extrusion Data Sheets. This work is documented by Exhibit 25, which is the Extrusion Data Sheet.

47. On **April 20, 1994**, Robert Ainsworth held a team meeting for the .014 Platform balloon dilatation catheter project, for which we were developing an extruded engineering thermoplastic shaft.

48. On **April 25, 1994**, at the request of Jeong Lee, ACS employee T. Tomas extruded additional polyethersulfone ("PES") material into tubing to be tested for suitability as the proximal shaft of a balloon dilatation catheter. Exhibit 26 documents this work.

49. On **April 27, 1994**, Robert Ainsworth called a meeting of the ACS employees working on the New .014 Platform catheter shaft. His day timer page, attached as Exhibit 27, documents this work. On the same day, Dr. Stone, an outside consultant, used .014 Platform over-the-wire prototype balloon dilatation catheters respectively having proximal shafts made of PEEK and of Elastinite® nickel-titanium alloy. Exhibit 6 documents this work on page A14.

50. On **April 28, 1994**, ACS employee Eric Leopold evaluated the performance of a coaxial RX catheter (which would have had an engineering thermoplastic proximal shaft) versus an elliptical RX catheter. This evaluation was later cited as a basis for electing the use of PEEK as a proximal shaft on a rapid exchange ("RX") catheter. This work is documented in Exhibit 6 at page A10. On the same day, a material test was carried out on a PEEK tubing sample by Ted Slater of the Shaft Technology Group at ACS to determine its suitability for use on

the proximal shaft of a balloon dilatation catheter. This work is documented by Exhibit 28, which is a Materials Test Report. On the same day, PPS tubing was similarly tested for the same purpose. This is also documented in Exhibit 28.

51. On or before **May 5, 1994**, Daniel L. Cox, another member of Robert Ainsworth's project team for the Low Profile Shaft project, prepared a memorandum. In that memorandum, he reported the results of his experiments on the effect of some critical process and design conditions on the intermediate junction from a PEEK proximal shaft to a polyethylene distal shaft for a balloon dilatation catheter. Exhibit 29 documents this work.

52. On **May 9, 1994**, at the request of Jeong Lee, ACS employee T. Tomas extruded Victrex PEEK tubing having the characteristics and process conditions specified in Exhibit 30.

53. On **May 13, 1994**, Ted Slater of the Shaft Technology Group tested the mechanical properties of the PEEK tubing referenced as 10-581, which is the material extruded as indicated in Exhibit 30. The particular sample tested is noteworthy because the elongation at break ranged from 2.03 to 2.43 inches per inch (ipi), with an average value of 2.22 ipi. These numbers translate to percent elongation numbers from 203% to 243%, average 222%. These tests were carried out specifically on tubing, as opposed to standard injection-molded mechanical property samples. This data indicates that the particular thin-walled extruded tubing produced here had far better elongation properties than the same material in the standard form for which properties are typically reported by the material manufacturer.

54. Also on **May 13, 1994**, inventor Wasicek ("L.W.") determined that a particular catheter design he had jointly developed, which previously had not specifically been contemplated to include a PEEK proximal shaft, could indeed have

such a proximal shaft. The hand-written notation "such as PEEK" near the middle of Exhibit 31, a copy of a previously submitted invention disclosure form, demonstrates this.

55. On **May 16, 1994**, Cathy Rincon, an in-house patent attorney at ACS, received the disclosure now marked as Exhibit 31, as indicated by her notation "read and understood" and her name and date in the lower right-hand corner of the document.

56. On **May 17, 1994**, Cathy Rincon sent this document to Edward Lynch, the attorney who would draft a patent application on the engineering plastic proximal shaft catheter. This document was sent to Mr. Lynch on **May 17, 1994**, as documented in the upper right-hand corner of Exhibit 31.

57. On **May 17, 1994**, at the request of Jeong Lee from Robert Ainsworth's project team, ACS employee T. Tomas extruded PEEK tubing under the conditions described in Exhibit 32. In this particular extrusion work, as Exhibit 32 indicates in handwriting at the bottom, ACS was experimenting with various process conditions "to verify the very best method to obtain better surface." The same handwritten notation indicates, "all samples were taken by Steve Schaible for evaluation". The second Exhibit 32 documents that after this experimentation a very good extrusion run was obtained.

58. On **May 19, 1994**, inventor Wasicek reported to others and us the results of Tinius Olson data that he measured for PEEK tubing extrusions having different air gaps, as reported in Exhibit 32. Tinius Olson data is a measurement of the susceptibility of the material to kinking. This work is documented by a memo with attachments dated **May 19, 1994**. The memo is attached as Exhibit 33.

59. From **May 19 to May 23**, **1994**, ACS employee Lucy Mariano carried out and reported on differential scanning calorimeter ("DSC") testing of PEEK tubing samples to determine the result of different extrusion conditions as reported in Exhibit 32. This full date range is shown on page 3 of Exhibit 34, which shows a revision date of **May 19, 1994,** on the third page on the third line from the top and a final date of **May 23, 1994**, at the bottom of the page. The second page of the report, in the top caption, also indicates a revision date of **May 20, 1994**. This work is documented in Exhibit 34.

60. Exhibit 6 at page A15 documents that, on **May 20, 1994**, a heart model test that was carried out using a balloon dilatation catheter prototype having a PEEK proximal shaft. This work is also documented in Exhibit 35, near the end, where Eric Williams entered the test report into a laboratory notebook on **June 21, 1994.**

61. On **May 25, 1994**, inventor Wasicek issued a memorandum in which he summarized testing conducted under his direction to determine how to neck down and expand PEEK extrusions. These are operations necessary to fabricate a two-part shaft, as by necking down one end of an extrusion and expanding the corresponding end of another extrusion which are to be joined to form the shaft of a balloon dilatation catheter. This work is documented in Exhibit 36. Also on **May 25, 1994,** we and other ACS employees conducted a technical review meeting to consider the work that had been done and the work that remained to be done to complete the development of a PEEK proximal shaft for a balloon dilatation catheter. Exhibit 37 documents this technical review. This document also documents some of the many steps required to develop an engineering plastic proximal shaft.

62. On or before **May 27, 1994**, we prepared a joint invention disclosure for a proximal shaft of a balloon dilatation catheter fabricated from an engineering thermoplastic polymer having improved properties. This invention disclosure is provided as Exhibit 38. This invention disclosure was reviewed and assigned a

docket number on **June 1, 1994**, as indicated by the notations of Cathy Rincon in the lower right corner of each page. Also on **May 27, 1994**, Exhibit 6 at page A16 notes that a heart model test was carried out using an over-the-wire ("OTW") catheter with a PEEK proximal shaft. Heart model work on this date is also documented in Exhibit 35, in entries dated **June 24, 1994**.

63. Monday, **May 30, 1994**, was Memorial Day, a regularly scheduled holiday for employees at ACS.

64. On **June 1, 1994**, Cathy Rincon sent Exhibit 38, which was then identified as 10000, to Edward Lynch. Exhibit 39 documents this activity. Mr. Lynch is the patent attorney who prepared and filed the application leading to the present patent. Also on **June 1, 1994**, Cathy Rincon sent a memo to us identifying the invention disclosure as docket number 10000 and indicating that any developments from additional work on the project should be communicated to her for incorporation in the resulting patent application. This memorandum is attached as Exhibit 40.

65. Although an invention disclosure had been filed and forwarded to Mr. Lynch for preparation of a patent application, work continued on optimizing the PEEK proximal shaft of a balloon dilatation catheter design.

66. On **June 7, 1994**, following substantially the same procedure as before, ACS employee T. Tomas carried out a series of extrusion tests in which he made various tubing from PEEK. This work is documented in Exhibit 41.

67. On **June 8, 1994**, Robert Ainsworth called a meeting on the .014 Platform project as identified above. This project involved the development of a PEEK proximal shaft at this point. Exhibit 42, a page from Robert Ainsworth's day timer page for that date, documents this meeting. Also on **June 8, 1994**, a large variety of

additional PEEK extrusion work was requested or done. These requests are documented in Exhibit 43.

68. On or about **June 9, 1994**, inventor Wasicek issued a report entitled "Alternative Extrusion Grade Resins for PEEK", in which he summarized efforts to determine whether some other extrusion grade engineering thermoplastic resin would provide a better performing proximal shaft than the PEEK material. This memorandum also confirms that work was carried out from **January 14, 1994**, to the date of the memo. The memo is attached as Exhibit 44. See also Exhibit 4, where a copy of the memo mounted in a laboratory notebook indicates that it was received by no later than **June 9, 1994.**

69. On **June 10, 1994**, Dan Cox completed a drawing of the ".014 Platform Elliptical OTW" (over-the-wire balloon dilatation catheter). This drawing is found in Exhibit 35, at the 6/24/94 entry. Also on **June 10, 1994**, Robert Ainsworth spent part of the day reviewing laboratory notebooks, including documentation for the PEEK proximal shaft work. This is indicated by Robert Ainsworth's day timer page for that date, attached as Exhibit 45.

70. On **June 15, 1994**, Inventor Tai Cheng reviewed and witnessed some of the laboratory work of Eric Williams evaluating various potential shaft materials for balloon dilatation catheters. Among the materials documented in this laboratory work was extruded PEEK material. This work is documented by Exhibit 35, pages 55-59.

71. On Wednesday, **June 15, 1994**, Robert Ainsworth held a staff meeting regarding the .014 Platform project that at this time had a PEEK proximal shaft. On the same day Robert Ainsworth also learned that Ted Slater, who performs much of the material testing, was on vacation at least on **June 15, 1994.** Robert Ainsworth

believes he was on vacation at least for the week of **June 13 to June 17, 1994**. Exhibit 46 documents his vacation.

72. On **June 17, 1994**, ACS employee T. Tomas extruded two different samples of PEEK tubing for use in prototyping balloon angioplasty catheter proximal shafts. Exhibit 47 documents this work.

73. On **June 20, 1994**, ACS employee T. Tomas extruded additional PEEK tubing. Exhibit 48 documents this work. Also on **June 20, 1994**, heart model testing was carried out on a balloon dilatation catheter prototype having a PEEK proximal outer shaft. This work is documented by Exhibit 5 at page A16.

74. Robert Ainsworth took a regularly scheduled two-week vacation from **June 20, 1994, through July 4, 1994**, returning to work on **July 5, 1994**.

75. On **June 21, 1994**, Eric Williams' notebook documents the construction of a balloon dilatation catheter prototype having a PEEK proximal shaft.

76. On **June 24, 1994**, additional heart model testing was carried out with two prototype balloon dilatation catheters having PEEK proximal shafts. Exhibit 5 documents this work at pages A14-A15.

77. On **July 1, 1994**, additional heart model testing was carried out at ACS, using a balloon dilatation catheter having a PEEK proximal shaft. Exhibit 5 documents this work at page A16.

78. **July 4, 1994**, was Independence Day, a regularly scheduled holiday for employees at ACS.

79. On **July 5, 1994**, ACS's patent department revised the docket number of the invention disclosure attached as Exhibit 39, renumbering it from disclosure 10000 to disclosure 10040. The change was communicated to Mari Kleineidam, who is an administrative assistant for patent attorney Edward Lynch. Exhibit 49 documents this activity.

80. On **July 6, 1994**, Robert Ainsworth held a status meeting regarding the .014 Platform, which would have included discussion of progress on a PEEK proximal shaft catheter that we were developing at that time.

81. On **July 8, 1994**, additional heart model testing was carried out for the Platform over-the-wire catheter, which at that time had a PEEK proximal shaft. This work is documented by Exhibit 5 at page A17.

82. On **July 11, 1994**, Robert Ainsworth held a meeting at ACS with his project team to discuss an intermediate shaft ("IM") design for a new .014 Platform balloon dilatation catheter having a PEEK proximal shaft. The intermediate shaft is another portion of a certain type of balloon dilatation catheter. This activity is documented by his day timer page of **July 11, 1994,** attached as Exhibit 50.

83. On **July 13, 1994**, Robert Ainsworth held a team meeting to discuss the progress of what by then we were calling the "New .014" catheter shaft design. By this time, we had determined that we would proceed with further development of the PEEK proximal shaft, as opposed to other thermoplastic or metallic proximal shafts we had been considering previously. My day timer page dated July 13, attached as Exhibit 51, documents this activity.

84. On **July 18, 1994,** Robert Ainsworth called a meeting at ACS to discuss the progress of the PEEK proximal shaft catheter projects. This activity is documented by Robert Ainsworth's day timer page of **July 18, 1994**, attached as

Exhibit 52. That Exhibit also indicates that Robert Ainsworth called Dennis Harrison regarding the Victrex meeting (Victrex was the trade name for the PEEK material we were using). On the same day, ACS employee T. Tomas extruded additional engineering thermoplastic material, this time PEK, at the request of Mr. Scheible. Exhibit 53 documents this work.

85. On **July 21, 1994**, Robert Ainsworth held a meeting to discuss the use of Victrex PEEK material for the proximal shaft of a balloon dilatation catheter. This meeting is documented by Robert Ainsworth's day timer page of that date, attached as Exhibit 54. On the same day, Ted Slater of our team carried out materials testing of PEEK material obtained from Amoco. We obtained very favorable results for "strain at break," which is a different way of expressing elongation. For example, on page 3 of Exhibit 55, near the foot of the second column from the right, an average elongation of 286% is indicated, with a range from 233% (run 7) to 328% (run 5). We thus obtained far better elongation properties for extruded PEEK tubing than the published specifications for PEEK.

86. On **July 22, 1994**, Robert Ainsworth met with Cathy Rincon of ACS's patent department. Robert Ainsworth believes that this is when he reviewed the patent application that had been drafted by Edward Lynch. This patent application was thus drafted diligently after our invention disclosure was sent to Mr. Lynch on **June 1, 1994**. On the same day Robert Ainsworth also met with Dennis Harrison regarding the Amoco source for PEEK material as referred to in Exhibit 55. These events of **July 22, 1994** are referred to on Robert Ainsworth's day timer page for that date, attached as Exhibit 56.

87. On **July 25, 1994**, Edward Lynch filed the patent application he had drafted for us. The application was U.S. Serial No. 08/280,210, which later issued as U.S. Patent No. 5,554,121.

88. Exhibit 6, a report dated **August 24, 1994**, provides additional documentation of activities that occurred during the diligence period from before **January 20, 1994,** to **July 25, 1994,** to reduce our invention to practice. For example, Exhibit 6, pages 25-26, reports that Drs. Kirk Garratt and Stuart Higano carried out additional animal studies at the Mayo Clinic on **July 29, 1994**. In that work, balloon dilatation catheter prototypes with PEEK proximal shafts were reported to perform better than two commercial catheters, the SCIMED COBRA and the MEDTRONIC 14K catheters. Exhibit 6 indicates, "The animal study results are consistent with in-house modeling." Exhibit 6 at page 18 shows that the goals of the research to develop the PEEK proximal shaft were to develop a shaft having a relatively high stiffness, yet high kink resistance. This page also indicates that efforts were made to qualify ACS to manufacture the PEEK tubing in-house instead of relying on a tubing fabricator. On page 38, Exhibit 6 shows a project schedule indicating that concept development was carried out in the **first and second quarters of 1994**.

89. As the foregoing records and statements show, we worked diligently during the entire diligence period, directly and through the efforts of other ACS employees, to develop, build, and test a balloon dilatation catheter having an engineering thermoplastic shaft as described in our patent.

Reduction To Practice

90. On **July 25, 1994**, Edward Lynch filed our patent application leading to the present patent. On information and belief, the filing of this patent application constitutes reduction to practice of our invention.

91. After our patent application was filed, we diligently continued to develop the PEEK proximal shaft catheter. This work progressed all the way to commercialization. ACS commercialized the "Concorde" balloon dilatation catheter having a PEEK proximal shaft (the trademark for a PEEK proximal shaft was

"PEAK") in late **1995** or early **1996**. Exhibit 57 – a brochure for the Concorde catheter, specifically mentioning its "PEAK" proximal shaft on the back cover, documents this commercialization. ACS later commercialized the ACS Tx2000 balloon dilatation catheter, which also had a "PEAK" proximal shaft. Exhibit 58 documents the ACS Tx2000 commercialization.

92. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent.

DATE	Robert Ainsworth
8/23/08	Lawrence Wasicek
DATE	Lawrence Wasicek

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